

# PROTECTING PATIENTS GLOBALLY

Selecting the most appropriate Sterile Barrier System (SBS) for use in the Central Sterilization Service Department (CSSD) is a challenging responsibility and plays a key role in infection prevention and patient safety.

Ahlstrom-Munksjö single use sterilization wraps help to prevent microorganisms (bacteria, viruses, spores) from easily gaining access to the tray contents, allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation.

# Ahlstrom-Munksjö Reliance<sup>®</sup> Wrap and sterilize your medical devices with confidence

Our Reliance® product range is comprised of various types of fabric, manufactured from 100% cellulose, cellulose + synthetic and 100% synthetic fibers. Our wide range and combination of sterilization wraps enables our customers to select the most appropriate Sterile Barrier System to meet their requirements.

### **Applications**

- Sterilization wraps for terminally sterilized medical devices
- Filter for containers
- Overwrap for single use Custom Procedure Trays (CPT)
- Tray liner for moisture absorption and protection of the tray

### **Our Technologies**



#### **Benefits and Characteristics**

- Facilitate the wrapping of medical instruments and devices
- · Allow sterilization due to good penetration and removal of sterilizing agent
- Maintain sterility of medical devices during handling and storage
- Enable aseptic presentation at the point of use



#### **Sterilization Methods**

The Sterile Barrier System products are to be used for wrapping medical devices, which can be terminally sterilized by the following methods:











We recommend that the end user validates the final packaging system as suitable with the intended sterilization process to comply with international standards as per ISO 11607 part 2.

#### Registrations and declarations

#### MDR 2017/745

Wrapping material are Medical Device Class I according to the classification rule 1 of Annex VIII from REGULATION (EU) 2017/745.

All products are registered at "Agence Nationale de Sécurité du Médicament" in France.

#### ISO 11607-1: 2019

Packaging for terminally sterilized medical devices. Part. 1: Requirements for materials, sterile barrier systems and packaging systems.

#### EN 868-2: 2017

Packaging material for terminally sterilized medical device. Part. 2: Sterilization wrap requirements and test methods.

#### **Additional information**

#### Latex free

All our products are latex free - including synthetic latex materials or natural rubber materials containing any of the proteins linked to Types I & IV latex allergies.

#### **Traceability**

Our production system ensures complete traceability of products via a LOT number printed on each delivered box, providing information relating to the production cycle. All data needed for effective tracking of a single box and identification is contained within the bar code on the external packaging.

#### Third party certifications

All our products received certification of compliance from:





# **CREPE PAPER**

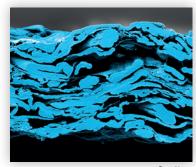
# **Excellent barrier properties with moisture absorption capacity**

Ahlstrom-Munksjö Reliance® crepe paper is made with more than 97% of cellulosic fibers and wet strength and sizing agents.

Cellulosic fibers create a tortuous path for excellent sterility maintenance and bacterial barrier.

It is available in Standard or Sensitive version: with an offline micrexing process, our Sensitive crepe paper is softer with improved drapeability.

Surface



Section

#### **Benefits and Characteristics**

- Best in Class bacterial barrier with BFE >99% in double layer (BFE: Bacterial Filtration Efficiency as per ASTM F2101 - 19)
- Helps to prevent wet-packs thanks to cellulosic material
- Cost-effective wrapping solution









# Ahlstrom-Munksjö Reliance® Crepe paper range

### **STERILIZATION WRAP: TRAY LINER:** Reliance® Crepe Reliance® Crepe Trayliner Light (R310) (R309) 60 gsm 80 gsm

Reliance® Crepe Sensitive (R310S) 60 gsm

Reliance® Crepe Trayliner Medium (R309) 110 gsm Reliance® Crepe Trayliner Heavy (R309S) 140 gsm





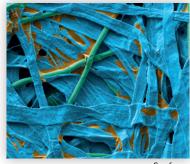
# WETLAID NONWOVENS

### Softer and stronger cellulose-based material

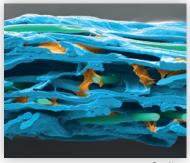
Ahlstrom-Munksjö Reliance® Wetlaid Nonwovens are made with 70% cellulose, 20% synthetic binder and 10% PET fibers.

Cellulosic fibers create a tortuous path for excellent sterility maintenance when synthetic binders and PET fibers bring more strength and softness to the product

Available in two colors and three basis weights, all our wetlaids are micrexed for increased drapeability and comfort.



Surface



Section

### **Benefits and Characteristics**

- Helps to prevent wet-packs thanks to cellulosic material
- Soft and strong thanks to synthetic fibers and binders
- Low lint according to ISO 9073-10: 2003









TRAY LINER:

(R308)

72 gsm

Reliance® Dextex Tray Liner

### Ahlstrom-Munksjö Reliance® Wetlaid range

#### **STERILIZATION WRAP:**

#### Reliance® Dextex 100

(R335)

52 gsm





(R345)

57 gsm

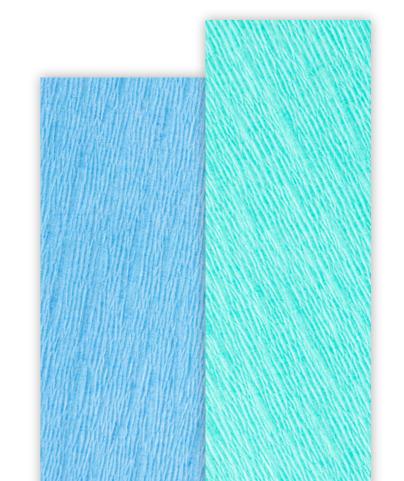


#### Relignce® Dextex 300

(R360)

67 gsm







# SMS - SPUNBOND MELTBLOWN SPUNBOND

# Strong and durable, with low lint and high barrier

Ahlstrom-Munksjö Reliance® SMS is 100% polypropylene and treated to resist static charge build-up. It does not contain natural fibers (cellulose) or synthetic binder.

The key to the barrier protection of the SMS are the three meltblown layers of microscopic fibers, delivering a tortuous path for a consistent bacteriological barrier to maintain sterility.

It is available in two colors and six different basis weights to satisfy different user requirements.



Surface

### **Benefits and Characteristics**

- Liquid repellent and antistatic according to ISO 811: 2018 and IST 40.2
- High strength according to ISO 1924-2 : 2008, ISO 1974 : 2012 and ISO 2758 : 2014 to avoid rips, tears or punctures
- Drapeability according to ISO 9073-9: 2008









Ahlstrom-Munksjö Reliance® SMS range

Reliance® SMS 100

(R430)

35 gsm



Reliance® SMS 200

(R440) 43 gsm



Reliance® SMS 300

(R450) 50 gsm



Reliance® SMS 400

(R460) 60 gsm



Reliance® SMS 500

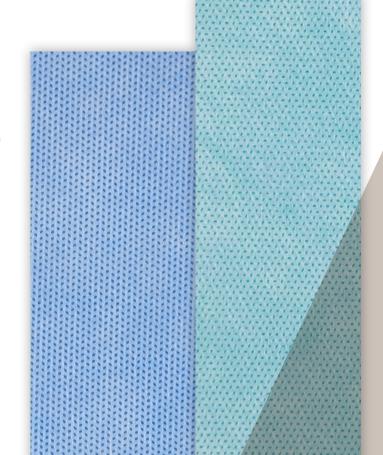
(R470) 70 gsm



Reliance® SMS 600

(R480) 85 gsm





# **AHLSTROM-MUNKSJÖ RELIANCE® TANDEM**

### Interleaved sterile barrier system solutions

Ahlstrom-Munksjö Reliance® Tandem combines different colors to provide the optimal combination for sequential wrapping, increasing efficiency and productivity.

The use of two colors clearly differentiates between the two layers during transport, storage and in the operating room allowing damage to be easily seen.

#### **Benefits and Characteristics**

- Color coding for improved efficiency the outer wrap and the inner wrap, which is sterile and suitable to be used in the operating room, have two different colors for easier identification.
- Simplified stock and purchase processes hospitals can save space and time using a single stock of two-colored layers.
- Increased patient safety the superposition of the two colored layers easily allows any damages or punctures to be visualized.

# Interleaved colors and technologies: the right combination to your wrapping requirements

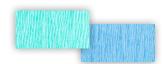
#### Same technology, different colors

Crepe paper, wetlaid and SMS can be interleaved with different colors to ensure the benefits associated to visual differentiation.

#### Reliance® Tandem Crepe



#### Reliance® Tandem Dextex



#### **Reliance® Tandem SMS**



#### Combining different technologies for improved performance

Cellulose, featuring high moisture absorption, can be combined with SMS to offer improved strength, combining the best of the two worlds.

Crepe / Wetlaid \_\_\_\_\_

Tandem

Crepe Sensitive / Dextex 200

(R310S / R345) Crepe / Wetlaid



Crepe / SMS \_\_\_\_\_

Tandem

Crepe / SMS 200

(R310/ R440) Crepe / SMS



Wetlaid / SMS \_\_\_\_\_

**Tandem** 

Dextex 100 / SMS 300

(R335 / R450) Wetlaid / SMS



# AHLSTROM-MUNKSJÖ RELIANCE® SOLO

# Bonded system for simultaneous wrapping

Ahlstrom-Munksjö Reliance® Solo is composed of two bonded sheets of SMS for easy to use, simultaneous wrapping.

Like sequential wrapping, Reliance® Solo creates a tortuous path, delivering aseptic opening at the point of use.

Two colors allow for easy identification of damage from transport/storage and wrong handling.

#### **Benefits and Characteristics**

- Simplified wrapping process
- Simultaneous aseptic unwrapping in the operating room
- High strength according to ISO 1924-2: 2008, ISO 1974: 2012 and ISO 2758: 2014 to avoid rips, tears or punctures
- Lotcode printed on every application

### Ahlstrom-Munksjö Reliance<sup>®</sup> Solo range

#### Reliance® Solo 100

(Solo 833) SMS

35 + 35 gsm



#### Reliance® Solo 200

(Solo 844) SMS

43 + 43 gsm



#### Reliance® Solo 300

(Solo 855) SMS

50 + 50 gsm



#### Reliance® Solo 400

(Solo 866)

SMS

60 + 60 gsm



#### Reliance® Solo 500

(Solo 877)

SMS

70 + 70 gsm



#### Reliance® Solo 600

(Solo 888)

SMS

85 + 85 gsm





# **OUR GLOBAL PRESENCE**

# Manufacturing, converting and servicing: reaching end users worldwide

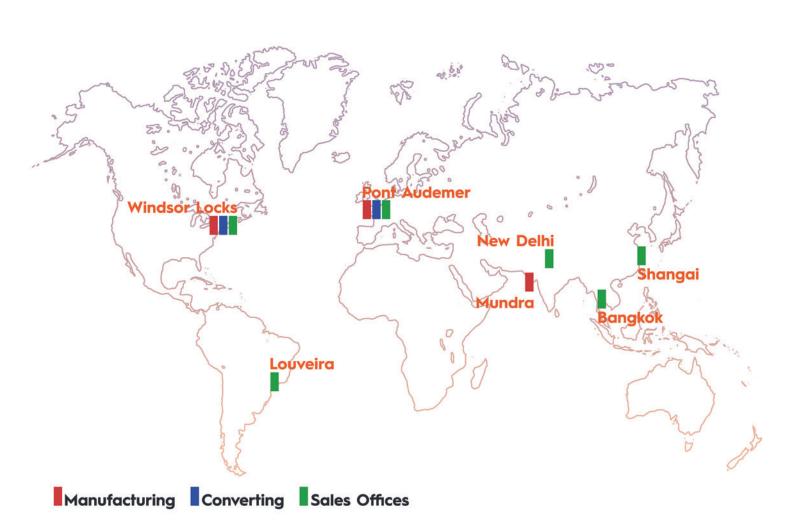
We manufacture, convert and have representation globally with three manufacturing sites dedicated to the production of fiberbased materials for sterilization wraps.

Ahlstrom-Munskjö has two state-of-the-art fully automated converting lines:

- Windsor Locks plant in Connecticut, USA to serve Americas and export markets under FDA requirements
- Pont Audemer plant in Normandie, France to serve Europe and export markets according to CE requirements

#### Our plants comply with the following standards:

Windsor Locks:	Pont Audemer:	Mundra:
ISO 13485 : 2016	ISO 13485 : 2016	ISO 13485 : 2016
ISO 9001 : 2015	ISO 9001 : 2015	ISO 9001 : 2015
ISO 14001 : 2004	ISO 14001 : 2015	ISO 14001 : 2015
PEFC, FSC, SFI	ISO 45001 : 2018	ISO 45001 : 2018
FDA Registered Site for Medical Devices	ISO 50001 : 2001	
	FSC™	



# **HOW TO USE\***

#### Prior to use

- Remove material from the packaging minimum two hours prior to use
- Examine wrap and discard if damage or extraneous matter is detected
- Thoroughly clean and dry items to be wrappedl.

#### **Folding Instructions**

For wrapping techniques, please refer to our Instructions for Use and the ISO TS 16775 : 2014 document, annex B : Guidance on the application of ISO 11607-1 : 2019 and ISO 11607-2 : 2019 in health care facilities.

#### Safety instructions and disposal

The product is non-toxic, nonhazardous and considered harmless as per ISO 10993-1: 2018.

Waste disposal must be in accordance with local regulations. Suitable for incineration as per EN 13431: 2004.

The product is combustible in oxygen-rich environments and when a source of ignition is applied to the fabric. Therefore, to avoid fire, the product should be kept away from heat, sparks and open flame. If fire does occur it can be extinguished by normal means.

#### **Precautions**

- Do not open carton or package with a sharp knife, knives can easily damage the wrap.
- The box has a tear tape to be easily opened.
- Do not use in the presence of flammable anesthesia..

### **Sterility Maintenance**

Real-time testing supports maintenance of package sterility for 180 days, provided package integrity is maintained.

Reliance® sterilization wraps range has been tested by third party laboratories for Time and Event Related Sterility Maintenance, ensuring six months of sterility maintenance. These tests have been performed to the best of our knowledge of hospital processes, providing end user has validated its sterilization process including forming, sealing and assembly of its packaging system according to ISO 11607-2: 2019.

\* Please refer to our IFU for complete instructions.

### Ahlstrom-Munksjö in brief

Ahlstrom-Munksjö is a global leader in fiber-based materials, supplying innovative and sustainable solutions to its customers. Our mission is to expand the role of fiber-based solutions for sustainable everyday life. Our offering includes filter materials, release liners, food and beverage processing materials, decor papers, abrasive and tape backings, electrotechnical paper, glass fiber materials, medical fiber materials, diagnostics and energy storage solutions, as well as a range of specialty papers for industrial and consumer end-uses. Our annual net sales is about EUR 2.7 billion and we employ some 7,800 people. Read more at www.ahlstrom-munksjo.com



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